PKS 6/25/00 pmsg HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
8600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4500
FAX: 504-253-4566

June 27, 2000

WARNING LETTER NO. 2000-NOL-25

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Dr. George Christopher Ball, President
Clinic for Women of Central Mississippi, P.A.
1820 Hospital Drive
Jackson, Mississippi 39204

Dear Dr. Ball:

We are writing to you because on June 1, 2000, your facility was inspected by a representative of the State of Mississippi, acting on behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- **Processor QC records were missing 14 consecutive days for the [redacted] Processor;**
- **Processor QC records were missing 14 out of 22 days of operation during the month of April 2000; and,**
- **[redacted] Quality Control (QC) records were missing for eight (8) weeks for unit 2**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems have been identified as Level 1, because they identify failures in meeting significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging

your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

Facilities must establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility. Facilities with screen-film systems are required to perform and evaluate a processor performance test on each day examinations are conducted and before any clinical films are processed. Also, an image quality evaluation test must be performed at least weekly using an FDA-approved phantom.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to **correct** all of the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations; and,
- include sample records that demonstrate proper record keeping procedures, relating to quality control (Phantom QC and Processor QC).

Please submit your response to:

Patricia K. Schafer, Compliance Officer
U.S. Food & Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127
Telephone: (504) 253-4519

Stacy G. Marshall, MQSA Auditor
U.S. Food & Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127
Telephone: (504) 253-4500

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U. S. Food and Drug Administration, Post Office Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Stacy G. Marshall at (504) 253-4554.

Sincerely,

Carl E. Draper
District Director
New Orleans District